

Standard Costs for Components of the Process for the Review of Human Drug Applications ¹ (\$000)

Revised to incorporate FY 2004 and FY 2005 Standard Costs

Estimates Made Pursuant to Section 736(d)(2) of the Federal Food, Drug, and Cosmetic Act

| Submission Type | <i>All determined on the basis of the Arthur Andersen model developed in 1993</i> | | | | | | | | <i>KPMG Model</i> | | <i>From Time Rpt.</i> | | |
|----------------------------------|---|---------|---------|---------|---------|---------|---------|---------|-------------------|---------|-----------------------|---------|---------|
| | FY 93 | FY 94 | FY 95 | FY 96 | FY 97 | FY 98 | FY 99 | FY 00 | FY 01 | FY 02 | FY 03 | FY 04 | FY 05 |
| Drug Applications | | | | | | | | | | | | | |
| IND | \$70 | \$79 | \$98 | \$97 | \$84 | \$94 | \$105 | \$119 | \$200 | \$212 | \$299 | \$203 | \$240 |
| NDA with Clinical Data - NME | \$887 | \$1,004 | \$1,243 | \$1,233 | \$1,065 | \$1,194 | \$1,328 | \$1,503 | \$1,920 | \$2,037 | \$2,116 | \$1,987 | \$2,456 |
| NDA with Clinical Data - Non-NME | \$298 | \$337 | \$417 | \$414 | \$358 | \$401 | \$446 | \$505 | \$929 | \$986 | \$746 | \$760 | \$685 |
| NDA without Clinical Data | \$127 | \$144 | \$178 | \$177 | \$152 | \$171 | \$190 | \$215 | \$261 | \$277 | \$561 | \$411 | \$476 |
| Supplement with Clinical Data | \$151 | \$171 | \$212 | \$210 | \$181 | \$203 | \$226 | \$256 | \$111 | \$118 | \$175 | \$142 | \$255 |
| Supplement without Clinical Data | \$6 | \$7 | \$8 | \$8 | \$7 | \$8 | \$9 | \$10 | \$8 | \$8 | \$18 | \$17 | \$17 |
| Biologic Applications | | | | | | | | | | | | | |
| IND | \$184 | \$230 | \$234 | \$266 | \$204 | \$173 | \$243 | \$175 | \$287 | \$279 | \$361 | \$400 | \$437 |
| BLA | | | | | | \$1,118 | \$1,568 | \$1,128 | \$2,788 | \$2,708 | \$4,394 | \$4,075 | \$4,492 |
| PLA | \$1,078 | \$1,345 | \$1,369 | \$1,560 | \$1,194 | \$1,016 | \$1,426 | \$1,026 | | | | | |
| ELA | \$177 | \$221 | \$225 | \$256 | \$196 | \$167 | \$234 | \$168 | | | | | |
| Supplement with Clinical Data | \$561 | \$700 | \$713 | \$812 | \$622 | \$529 | \$742 | \$534 | \$195 | \$190 | \$228 | \$367 | \$239 |
| Supplement without Clinical Data | \$34 | \$42 | \$43 | \$49 | \$38 | \$32 | \$45 | \$32 | \$31 | \$30 | \$21 | \$41 | \$42 |

¹ Standard costs include all costs associated with application review, including rent, overhead, and centrally funded costs. Method revised in FY 2001-2002 based on KPMG study, and in 2003 on time reporting data. Time reporting method revised with better allocation of indirect cost beginning in 2004.